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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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7590

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EXAMINER

BAHAR, MOJDEH

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 04/23/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/583,228

Applicant(s)

SETH, PAWAN

Examiner

Mojdeh Bahar

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z. 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's response to the first office action of May 22, 2001, and amendment submitted November 29, 2001 (Paper Nos. 5-6) and supplemental IDS of June 29, 2001 are acknowledged.

Applicant's amendment is persuasive to remove the rejection of claims 1, 9 and 11 under 35 USC 112, 2<sup>nd</sup> paragraph as far as it concerns the expression "sustained release".

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The expression "functional coating" in claims 1 is indefinite and one skilled in the art would not know what distinguishes a "functional coating" from any other coating.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morella et al. (USPN 5,378,474).

Morella et al. (USPN 5,378,474) teaches a substantially similar composition and process as those claimed herein. Morella et al. (USPN 5,378,474) teaches a sustained release

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pharmaceutical composition having a core element containing an antihypertensive agent such as Verapamil Hydrochloride, a methacrylic polymer (35-70% wt.), hydroxypropyl methylcellulose (4-20% wt.), polyethylene glycol (15-35% wt.) and a filler such as silicon dioxide (4-30% wt.), see claims 1, 2, 7 and 9 as well as Col.4, line 24. Morella et al. (USPN 5,378,474) also teaches that the active ingredient in the pharmaceutical composition reaches its maximum concentration between about 4 and about 30 hours, col. 24, claim 1 and that the bioavailability of the active agents in the pharmaceutical pellet is not compromised by food, col.7, lines 34-40. Morella et al. (USPN 5,378,474) further teaches a method of preparing the pharmaceutical composition, col. 12, lines 18-39.

Morella et al. (USPN 5,378,474) does not teach the particular composition containing the specific ingredients in the amounts herein.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the particular composition containing the specific ingredients herein in amounts herein.

One of ordinary skill in the art would have been motivated to make the composition claimed herein since a substantially similar composition is taught in the prior art. Morella et al. (USPN 5,378,474) teaches a similar composition which may contain an antihypertensive agent (including verapamil) and the excipients herein in amounts (wt. percentages) that overlap with those in the instant claims. The optimization of amounts of ingredients to be employed in a composition is considered within the skill of the artisan. The instant composition is not seen to patentably distinguish over the prior art, absent evidence to the contrary. No such evidence is seen.

***Response to Arguments***

Applicant argues that the transitional language in the amended claims (i.e., consisting essentially of) excludes compositions having significant amounts of a third polymer that would materially effect the novel characteristics of the invention. Note that the inclusion of a third polymer to a coating that itself is made of a polymeric as well as a non-polymeric component does not materially effect the novel characteristics of the invention. It merely increases the polymer to the non-polymer ratio of the coating. The therapeutic effects of the active ingredient, verapamil, is not at all affected. Moreover, the active ingredient is not compromised by food as indicated in the prior art reference. Therefore the inclusion of a third polymer to the composition does not materially affect the novel characteristics of the invention. Note that the instant claims do not exclude the inclusion of a third polymer so long as the novel characteristics of the invention are not materially affected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 Monday, Tuesday, Thursday and Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar  
Patent Examiner  
April 17, 2002

RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1280